approximately 30% t10,c12 octadecadienoic acid residues, at least approximately 30% c9,t11 octadecadienoic acid residues, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic and trans-trans octadecadienoic acid residues at positions R_1, R_2, and R_3, wherein said percentages are peak area percentages as determined by gas chromatography.

14. The composition of Claim 13, wherein said prepared food product is a bar.

15. The composition of Claim 13, wherein said prepared food product is a drink.

16. The composition of Claim 13, wherein said prepared food product is a snack food.

17. The composition of Claim 13, wherein said prepared food product is a frozen meal.

REMARKS

Claims 5-8 are at issue in the present application. For clarity, the rejections at issue are set forth by number in the order they are herein addressed:

1) Claims 5-8 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite;
2) Claims 5-8 are rejected under 35 U.S.C. §103 as allegedly being obvious over Nilsen et al. (U.S. Pat. No. 5,885,594) in view of Cook *et al.* (U.S. Pat. No. 5,554,646) and Timmerman *et al.* (WO98/49129) in view of Cook *et al.* (U.S. 5,554,646).

The Specification has been amended in response to the Examiner's objection to an informality. Support for the "residue" amendment is found in the Specification at page 21, lines 4-11, which describes triglycerides in which CLA is attached to a glycerol backbone, and in Examples 5 and 6, pages 37-39, which describes the production of CLA triglycerides containing CLA residues. Support for the percentage area amendment is found in the Specification at page 18, lines 18-25, and page 24, lines 23-28. Applicants believe the present amendments and following remarks traverse the Examiner's rejection of the Claims.

1. The Claims are Definite

Claims 5-8 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicants respectfully submit that this rejection is improper. The MPEP and Federal Circuit case law have made it clear that the definiteness of claim language must be analyzed, not in a vacuum, but in light of: 1) the content of the particular application's disclosure; 2) the teachings of the prior art; and 3) the claim interpretation that would be given by one possessing the ordinary level of skill in the art at the time the invention was made.[1] Applicants submit that application of this analysis leads to the conclusion that the Claims are definite. The specification teaches that the percentage of CLA isomers within a preparation can be determined by analysis of peak areas generated by gas chromatography analysis. Therefore, one of skill in the would clearly know the meaning of the term "percentage." Nevertheless, in order to advance the Applicant's business interests and without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the claims as originally submitted (or similar claims), Applicants have amended the Claims to specify that percentage is determined by the peak area percentage as assayed by gas chromatography (*e.g.*, GC-MS or Gas Liquid Chromatography).

2. The Claims are Non-Obvious

Claims 5-8 are rejected under 35 U.S.C. §103 as allegedly being obvious over Nilsen *et al.* (U.S. Pat. No. 5,885,594) in view of Cook *et al.* (U.S. Pat. No. 5,554,646) and Timmerman *et al.* (WO98/49129) in view of Cook *et al.* (U.S. 5,554,646). A *prima facie* case of obviousness requires the Examiner to cite a combination of references which (a) disclose all the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements precludes finding of a *prima facie* case of obviousness,

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[1] MPEP §2173.02, *See also In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 221 USPQ 1 (Fed. Cir. 1984); and *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 220 USPQ 303 (Fed. Cir. 1983).

and, without more, entitles Applicant to allowance of the claims at issue.[2] The claims are not obvious as the prior art cited by the Examiner satisfies none of the three elements above.

A. The Examiner has not Established a Motivation to Combine

When applying 35 U.S.C. §103, the cited references must be considered as whole and must suggest the desirability and thus the obviousness of making the combination.[3] Applicant further submits that references cannot be considered collectively until the Examiner points to some motivation to combine those references. The purpose behind this requirement is to prevent the Examiner from using the invention itself and hindsight reconstruction to defeat the patentability of the invention.[4] The Federal Circuit, in a recent decision, articulates this position:

> To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.[5]

Applicant submit that an obviousness rejection must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, all of the facts must be considered and the Examiner must supply the factual basis for the rejection. The Examiner may not, because he or she doubts that the

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[2] *See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

[3] *Hodash v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143, n. 5, 229 USPQ 182, 187, n.5 (Fed. Cir. 1986).

[4] The Federal Circuit, (*W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 [Fed. Cir. 1983]), also has stated that:

> To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

[5] *See In re Rouffet et al.*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998).

invention is patentable, resort to speculation, unfounded assumptions, or hindsight reconstruction to supply deficiencies in the factual basis for the rejection.[6]

Applicant believes that this is the situation in the present case. None of the prior art references cited by the Examiner provide any teaching or suggestion of compositions containing less than 1% of the 8,10; 11,13; and trans, trans isomers of CLA. Instead of supplying a factual basis for the rejection, the Examiner merely supplies an unfounded, **conclusory** motivation statement. With respect to the combination of Nilsen *et al.* and Cook *et al.*, the Examiner states:

> A person of ordinary skill in the art would have been motivated to make the combination of Nilsen et al. with acylglycerol compounds wherein the fatty acid moiety is a mixture of about equal amounts of c9,t11-octadecadienoic acid and c10,t12-octadecadienoic acid and employ the composition in feed for animals because both compounds are known to be useful in food or feed products. The optimization of the ratios is considered within the skill of artisan. Further, composition known to be useful in food products is reasonably expected to be useful in feed products for animals.[7]

The Examiner then used this exact same statement to support the combination of Timmerman *et al.* and Cook *et al.*[8]

Such conclusory statements do not meet the "motivation to combine" standard established by the Federal Circuit. Indeed, the Federal Circuit has made it clear that "[b]road, conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence.'"[9]

These conclusory statements made by the Examiner do not provide *reasons* why a person skilled in the art would combine the references to make compositions containing less than 1% of the 8,10; 11,13; and trans, trans isomers of CLA. Neither the Examiner's statements not the cited references adequately address this limitation. The Examiner does not provide a statement from the references showing the desirability of producing CLA

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[6] *See, In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967).

[7] Office Action, page 5.

[8] Office Action, page 6.

[9] *In re Dembiczak*, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999).

compositions containing less than 8,10; 11,13; and trans, trans isomers of CLA. Furthermore, the Examiner's statement that "optimization of ratios is considered within the skill of the artisan" is **completely unsupported and conclusory**. These types of statements are expressly forbidden by the Federal Circuit. Furthermore, the law states the Examiner that he/she is not one skilled in the art and that he/she must provide support for such statements.[10] The deficiency of the Examiner's motivation to combine rationale is underscored by the fact that the **same** motivation statement is used for the combination of **different** references. The statements made by the Examiner are clearly conclusory because they can evidently be applied to a variety of references. Accordingly, Applicants respectfully submit that the Examiner has not provided a proper motivation to combine. As such, the Examiner has not established a *prima facie* case of obvious and Applicants respectfully request that the claims be passed to allowance.

B. The Cited References Do Not Teach Each Element of the Claims

The Examiner has not established a *prima facie* case of obviousness because, even if it were proper to combine the references (and Applicants maintain the combination is improper), the references do not teach all of the elements of the Claims. The Examiner admits that "Nilsen et al. do not teach expressly the specific amounts of each of the two isomers, i.e., c9,t11-octadecadienoic acid and c10,t12-octadecadienoic acid, or the employment of the composition in animal feeds."[11] The Examiner then goes on to contradict this statement by stating that "Nilsen et al. do not use other isomers of conjugated linoleic acids. Therefore [they] meet the limitation set forth in claim 5 that the other isomers are present in amounts less than 1% is met."[12] Applicants query the Examiner as how it is possible to state that a reference does not teach the amount of isomers present in a composition and then claim that other isomers aren't present merely because they are not mentioned.

Applicants note that Nilsen *et al.* are completely silent as to the presence of other isomers in their CLA composition. This silence does not mean that other isomers are not

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[10] *See* MPEP 2144.03.

[11] Office Action, page 4.

[12] Office Action, page 4.

present. In fact, the passage cited by the Examiner contemplates all isomers of CLA. At column 3, line 63-Column 4 line 11, Nilsen *et al.* state:

> The term "conjugated polyunsaturated fatty acid residue", as used herein, is defined as fatty acid compounds, having 16 to 22 carbon atoms, and at least two double bonds, wherein said double bonds alternate with single bonds. Various positional and geometric isomers of conjugated polyunsaturated fatty acid residues involving the double bonds exist and are meant to be included herein. The conjugated polyunsaturated fatty acid residue octadecadienoic acid (18:2) is also known as conjugated linoleic acid (9-cis, 11-trans-octadecadienoic acid and/or 10-cis, 12-trans-octadecadienoic acid); octadecatrienoic acid (18:3) is also known as conjugated linolenic acid; and eicosatetraenoic acid (20:4) is also known as conjugated arachidonic acid. The above-described chemical and common names for these conjugated polyunsaturated fatty acid residues represent the same compounds and may be used interchangeably herein.

As can be seen, Nilsen *et al.* define "conjugated polyunsaturated fatty residue" to expressly encompass all the "various positional and geometric isomers." Therefore, Nilsen *et al.* do not teach CLA compositions containing less than a certain defined percentage of a subset of the "various positional and geometric isomers" of CLA.

These same arguments apply to the combination of Timmerman *et al.* and Cook *et al.* The Examiner again admits that "Timmerman *et al.* do not teach expressly the specific isomers employed in the acylglycerol compounds."[13] The Examiner then attempts to cure this admitted deficiency by claiming that "Cook et al. teach that both c9,t11-octadecadienoic acid and c10,t12-octadecadienoic acid, and their mixture are known to be beneficial for animal health, See particularly, column 1, lines 51-57."[14]

Applicants respectfully submit that like Timmerman *et al.*, Cook *et al.* are completely silent as to the actual isomer content of their CLA composition. The Examiner's attention is directed to Sugano *et al.*, attached at Tab 1. Comparison of Sugano *et al.* and Cook *et al.* reveals that Sugano *et al.* prepared CLA from purified linoleic acid by a method similar to that utilized by Cook *et al.* In both methods, conjugation was performed in ethylene glycol at 180°C. The main differences are that Cook *et al.* utilize NaOH as the catalyst, as opposed to the KOH used by Sugano *et al.*, and that Cook *et al.* heated the mixture for 2.5 hours, as

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[13] Office Action, page 5.

[14] Office Action, page 5.

opposed to the 2.0 hours used by Sugano *et al.*. Sugano *et al.* disclose that their CLA contained **18.6%** trans-trans isomers and **13.7%** other isomers, in addition to the c9,t11 and t10,c12 isomers. Applicants fail to understand how Cook *et al.* allegedly teach the "less than 1% of 8,10, 11,13 and trans-trans isomers of CLA" element of the claims when it is clear that methods similar to those utilized by Cook *et al.* result in a **different composition**.

The Examiner does not cure this deficiency by stating that "the optimization of the ratio of the compounds is within the skill of the artisan." Applicants respectfully submit that the Examiner is not one skilled in the art and is required to present support for this proposition.[15]

Applicants further note that the disclosure of Cook *et al.* is primarily directed to "active" isomers of CLA. As such, this disclosure **does not** rule out or otherwise address the fact that the compositions obtained by Cook *et al.* contain other isomers. For example, at Column 4, lines 1-9 Cook *et al.* specify that:

> The animal feeds and pharmaceutical or veterinary compositions for use in the method of the present invention are those containing the active forms of the free conjugated linoleic acids (CLA), especially the 9,11-octadecadienoic acid and 10,12 octadecadienoic acid or mixtures thereof . . . .

Furthermore, at Column 4, lines 50-55, Cook *et al.* specify:

> Theoretically, 8 possible geometric isomers of 9,11 and 10,12-octadecadienoic acid (c9,c11; c9,t11; t9,c11; t9,t11; c10,c12; c10,t12; t10,c12; and t10,t12) would form from the isomerization of c9,t12-octadecadienoic acid. As a result of the isomerization, only four isomers (c9,c11; c9,t11; t10,c12; and c10,c12) would be expected.

These passages are only directed to the so-called "active" isomers of CLA. These passages do not address all of the other isomers that are commonly formed when linoleic acid is isomerized. The existence of the other isomers in isomerized linoleic acid compositions is documented in the Sugano reference discussed above and in Examples 1-3 of the present application. Applicants contend that these passages from Cook *et al.* do not teach a composition containing only active isomers as the Examiner suggests. They simply discuss the so called "active" isomers of CLA.

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[15] *See* MPEP 2144.03.

For the reasons discussed above, Applicants respectfully submit that the cited references do not teach each element of the claims. As such, Applicants request that the obviousness rejection be removed and the claims passed to allowance.

C. The Cited References do not Provide Reasonable Expectation of Success

The cited references do not provide a reasonable expectation of success for obtaining the claimed compositions. The Federal Circuit has held that "obvious to experiment" is not the standard for obviousness.[16] The *Dow* court made it very clear that one must determine whether "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art."[17]

Applicants submit that one skilled in the art would not believe that a reasonable expectation of success existed for making the claimed CLA composition. Neither the combination of Nilsen *et al.* and Cook *et al.* nor the combination of Timmerman *et al.* and Cook *et al.* teach or suggest how to obtain a CLA composition containing less than 1% of 8,10, 11,13 and trans-trans isomers of CLA. Applicants respectfully submit that the above comparison of the Sugano reference and Cook *et al.* presents ample evidence that Applicants achieved an unexpected result in producing CLA comprising less than 2% of 8,10, 11,13 and trans-trans isomers of CLA.

Applicants contend that the cited references provide absolutely no guidance or suggestion as to whether the 8,10; 11,13; and trans, trans isomers of CLA should be minimized in the product and, indeed, how to actually minimize these isomers. As discussed above, the cited references do not address the isomer composition of CLA. Therefore, Applicants fail to understand how the cited references allegedly provide a reasonable expectation of success in producing the claimed compositions when the references neither discuss the 8,10 and 11,13 isomers or provide methods for reducing their concentration in CLA compositions.

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[16] *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988).

[17] *Id.* at 1531 (Emphasis added).

Accordingly, Applicants respectfully submit that the Examiner has not established a reasonable expectation of success for making the claimed invention. Therefore, Applicants request that the obviousness rejection be removed and the claims passed to allowance.

CONCLUSION

All grounds of rejection and objection of the Office Action of July 5, 2000 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the claims are in condition for allowance. Should the Examiner have any questions, or if a telephone conference would aid in the prosecution of the present application, Applicant encourages the Examiner to call the undersigned collect at 608-218-6900.

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